Start the conversation: Evaluating implementation of a multi-level PrEP initiative for Black cisgender women in New Orleans, Louisiana
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1. Introduction

Profound sexual health disparities exist for Black cisgender women living in Louisiana, where the rate of HIV diagnosis is more than 7 times higher than that of White women. New Orleans, Louisiana (NOLA) is heavily impacted by the HIV epidemic and is a priority jurisdiction for the Ending the HIV Epidemic (EHE) Initiative.[1] Yet PrEP awareness and uptake have been poor among Black cisgender women, including in NOLA.[2–4] Culturally-sensitive strategies are critically needed to reduce HIV infections among Black cisgender women.

In our 2019 NIH-funded Ending the HIV Epidemic Administrative Supplement grant, a team of collaborators—investigators, the Louisiana Department of Health, and members of NOLA's Black Women and PrEP (BWAP) Task Force—partnered to identify determinants to PrEP uptake among Black cisgender women in NOLA and implementation strategies to address them. The BWAP Task Force consists of 25 Black female community representatives of diverse backgrounds; many are engaged in PrEP-related efforts for Black women in NOLA. Informed by formative research findings from our qualitative interviews with Black cisgender women using and not using PrEP, the BWAP Task Force identified two main barriers to PrEP uptake: Black cisgender women do not know of other Black cisgender women taking PrEP, and Black women are not offered PrEP during routine medical care. The BWAP Task Force identified two linked strategies to "*Start the Conversation*" around PrEP: a social media campaign to increase awareness of Black cisgender women using PrEP and a provider combined-care model to encourage providers to discuss PrEP with Black cisgender women. The Task Force stressed the importance of using a multi-level approach that includes both patient and provider-level strategies.

We received NIH R34 funding to develop and evaluate implementation of the *Start the Conversation* PrEP initiative. A previous protocol focused on the development of the initiative (Duke: #Pro00109957; LSU: #2163). This protocol focuses on evaluating the implementation of the initiative at the Louisiana State University (LSU) GYN resident clinic based at the University Medical Center-New Orleans (UMCNO).

2. Study Objectives

The study objectives are to:

- Evaluate implementation outcomes from piloting the *Start the Conversation* Initiative
- Assess initial indicators of clinical effectiveness among patients engaged in the *Start the Conversation* Initiative

3. Initiative Overview

The *Start the Conversation* Initiative includes a PrEP combined-care model and a social media campaign.

PrEP combined-care model overview: We will train LSU GYN residents to (1) start the PrEP conversation with all potentially eligible patients (per CDC guidelines), (2) prescribe PrEP for interested patients, and (3) create a plan for PrEP follow up either at the GYN clinic or a local PrEP clinic. Patients will choose whether to receive follow-up care at the LSU GYN resident clinic or be referred to care at a local PrEP provider. We anticipate

providing a monthly training prior to each resident clinic block, with approximately 4 to 6 residents at each training.

We may also engage PrEP champions (e.g., a provider or resident at the GYN resident clinic) to follow-up on patients' laboratory assessments and whether they filled their PrEP prescription. The PrEP champion may contact the patient as part of regular patient care.

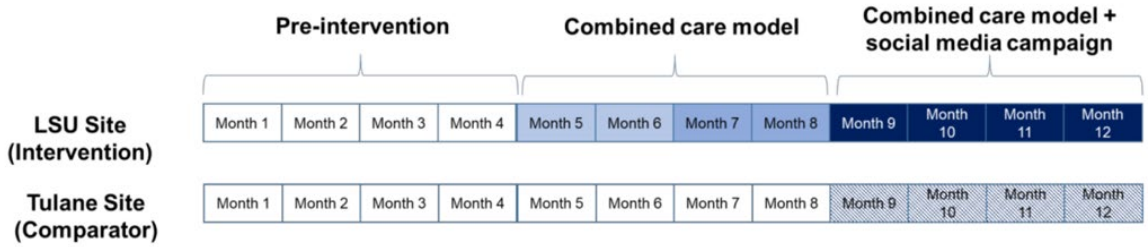
Social media overview: We will implement a social media campaign focusing on raising awareness about Black cisgender women engaging in PrEP care. The content and strategy were developed as part of our previous protocol (Duke: #Pro00109957; LSU: #2163). Selected members of the BWAP Task Force who are active influencers, other identified influencers, and local organizations will distribute all social media content via their standard channels and approaches for communicating with their followers (e.g., Facebook, TikTok). All social media content will link Black cisgender women to a PrEP navigator located at the Louisiana Department of Health Office of Public Health STD/HIV/Hepatitis Program's (SHHP). SHHP will refer women to a PrEP provider/location of their choice.

4. Study design

We will layer data collection and the implementation of the combined-care model and social media campaign over three phases. Phase 1 is the pre-intervention phase and it will last for 4 months (months 1-4). The only study activity during the pre-intervention phase is the collection of routine PrEP uptake data to establish a baseline for PrEP prescribing at the GYN residency clinics and local PrEP clinics. Phase 2 is the implementation of the combined-care model at the LSU GYN residency clinic at UMCNO for 4 months (months 5-8). Phase 3 adds implementation of the social media campaign in the NOLA area for 4 months (months 9-12); implementation of the combined-care model at LSU GYN residency clinic at UMCNO will continue during this time (Figure 1). The layered approach allows for an opportunity to assess the effect of the combined-care model, and subsequently, to what extent the social media campaign additionally engages Black women and builds demand for PrEP.

We also include a comparator arm to evaluate changes in PrEP uptake due to other secular trends in the area and increases due to the social media campaign. The three comparator clinics are: (1) another GYN resident program (Tulane Downtown GYN Clinic), (2) the UMCNO PrEP clinic (Clement, PI, is a provider), and the Tulane PrEP clinic.

Figure 1: Study design



5. Study Outcomes

We will assess both implementation outcomes (Table 1) and clinical outcomes (Table 2).

The implementation outcomes are guided by Proctor et al and include: acceptability, feasibility, appropriateness, adoption, fidelity, and maintenance.[5] These outcomes will be assessed qualitatively through in-depth interviews (IDIs), debriefing sessions with GYN residents and leadership, medical chart reviews and/or de-identified Epic queries, training records, discussions with the BWAP Task Force, and social media metrics.

Table 1: Implementation Outcomes

Outcomes	Measurement	Data sources & level of analysis
Acceptability	Satisfaction of complexity, content, relative advantage, and credibility of implementation strategies being delivered.	**Provider:** Debriefing sessions & IDIs **Patient**: IDIs **Community stakeholders:** Regular meeting with the BWAP Task Force
Feasibility	Fit from site perspective, suitability for everyday use, practicability.	**Provider:** Debriefing sessions & IDIs
Appropriateness	Perceived fit and relevance to needs of Black cisgender women and suitability for GYN residents to implement	**Provider:** Debriefing sessions & IDIs **Patient**: IDIs **Community stakeholders:** Regular meeting with the BWAP Task Force
Adoption	• # residents trained/# residents rotating through GYN clinic • # residents initiating PrEP/# residents rotating through GYN clinic • Time between training providers & their beginning to implement	**Provider:** Training records, chart review
Fidelity	• Time to implement: Average response time from social media inquiries by PrEP navigator • Completeness of combined care model delivery per eligible clients (% discussed PrEP; % provided PrEP counseling; % made a PrEP follow up plan; # monthly feedback sessions occurring) • Quality of implementation strategy delivery • Consistency of fidelity within and across providers	**Social media:** Records of inquiries, calls and responses; metrics (e.g., post frequency, specific post reach, likes and amplification rates as a marker of quality) **Provider:** Epic data pull, chart review (completion/consistency); IDIs (quality) **Patient:** IDIs (quality)
Maintenance	• Adoption (see above) by providers over time • Fidelity of completeness (see above) of delivery over time	**Provider:** Epic data pull, chart review
Reach	• # social media video views; # jingle plays; # campaign Facebook site visits	**Social media:** Platform metrics (e.g. Facebook, TikTok)

Table 2: Clinical outcomes, primary and secondary	
Primary	• Total number of women overall and number of Black cisgender women initiating PrEP at the LSU GYN clinic during the pre-implementation period (Phase 1: months 1-4) compared to during the two implementation period phases (Phase 2: months 5-8 and Phase 3: months 9-12). • Comparison of the difference in patient numbers at the LSU GYN clinic during pre-implementation and the two implementation period phases with the difference in patient numbers during the same time frame at the Tulane GYN clinic. • Comparison of the difference in patient numbers at LSU GYN clinic and UMC PrEP clinic combined to the Tulane GYN and Tulane PrEP clinics combined during the same time frame to further investigate trends outside of the GYN clinics potentially impacted by the social media campaign.
Secondary	• Proportion of PrEP-eligible women overall and Black cisgender women initiating PrEP at the LSU GYN clinic across the two implementation time periods (combined-care model only, Phase 2—months 5-8; combined care model plus social media company, Phase 3—months 9-12) • Proportion of women choosing follow-up care at the LSU GYN resident clinic versus transition to a local PrEP provider • Proportion of women initiating PrEP at the LSU resident GYN clinic who complete their first follow-up PrEP care visit (can only assess at the LSU GYN resident clinic or UMC PrEP clinic) • LDH navigator logs (number of contacts, number of appointments made through the PrEP navigator)

6. Data collection

Chart reviews, use of electronic medical records, and provider surveys

For baseline data collection (Phase 1, months 1-4), we will retrospectively collect data at the LSU GYN resident clinic, Tulane Downtown GYN Clinic, and the LSU PrEP clinic at the end of Phase 1 for the previous 4 months. Data will consist of the number of new PrEP prescriptions per month (overall among women and number of Black cisgender women specifically). No identifiable data will be collected. We may also collect baseline data for up to 12 months prior to Phase 2 initiation to compare trends over time.

Because the number of PrEP prescriptions among women at the Tulane Downtown GYN clinic and the Tulane PrEP clinic is extremely low, we will administer a survey to clinic leadership or another representative to gather the aggregate, de-identified data throughout implementation of this study. We will not access patient records at these sites. To collect data from the UMC PrEP clinic, in which Dr. Clement (study PI) is a provider, we will collect the de-identified data via provider survey if feasible (since numbers are also low), or if necessary, through patients' electronic medical records (EMR).

We will continue to collect data on PrEP prescriptions at the Tulane Downtown GYN Clinic, the Tulane PrEP clinic, and the LSU PrEP clinic until the end of Phase 3.

For data collection during the implementation phase (Phases 2 and 3, months 5-12) at the LSU GYN resident clinic, we will collect the number of new PrEP initiation counts for cisgender

women by date, race, and provider through provider notes. We will also collect data to inform the primary and secondary clinical and implementation outcomes (LSU site only) through Epic data pulls (i.e., provider note templates will incorporate 'smartlists' and 'smartphrases' with extractable data elements), and if necessary, provider notes and chart review of GYN patients seen. If chart review is required, and depending on the volume of patients seen, we may use a stratified random sampling approach to select patients for the chart review. Additionally, we may also track EMR prescription data to trend PrEP initiations and follow initiation patterns (and thus adoption metrics) across providers for all patients seen during the study period.

We anticipate that 32 to 48 LSU GYN residents will be trained in the combined-care model. The LSU GYN clinic at UMC sees 60 to 80 patients per week; it is estimated that ~30/week will be eligible for PrEP, of which we anticipate ~2 will be initiated per week. This will result in an estimated 2,400 women seen over the 8-months of implementation, of which ~1,000 will be PrEP-eligible and around 70 will take up PrEP in the GYN clinic.

In-depth interviews

We will also conduct IDIs with 12 GYN residents who were trained and 12 patients who were offered PrEP using the "Start the Conversation" guidance and materials.

LSU GYN residents and leadership: We aim to interview a diverse group of LSU GYN residents based on their varying experiences in starting a PrEP conversation with patients and prescribing PrEP. We will work with the residency program's PrEP leadership to identify and purposefully select residents to invite for the IDIs. This will be coupled with Epic data pull reviews to document adoption and fidelity of provider implementation during the pilot. Adoption and fidelity outcomes will be summarized by provider, including the number of PrEP conversations started and the number of PrEP prescriptions provided by patient demographics (i.e., race and age). Any patient information will be de-identified, and the list provided to study staff. We will aim to purposefully select (1) three residents who frequently started a PrEP conversation but did not prescribe PrEP, (2) three residents who infrequently started a PrEP conversation, and (3) three residents who frequently prescribed PrEP. Modifications in our selection process may be needed based on the number of residents who start a PrEP conversation or prescribe PrEP. Study staff will contact each selected resident to invite them to participate in an IDI. Interested residents will be connected to study staff to receive an information sheet about the study and scheduling. We will also interview members of the GYN leadership team, such as attending preceptors and the LSU GYN residency program director(s).

PrEP patients: We aim to interview a diverse group of Black cisgender women who initiated PrEP during the pilot based on their decisions on the location of their PrEP follow-up care and whether they attended their month 1 follow-up PrEP visit. Among Black women prescribed PrEP, GYN residents or leadership will inform patients that the PrEP program is part of a larger study and that they may be contacted by study staff for possible participation in an IDI. Using the list of women who initiated PrEP, the PrEP Champion or another provider will review women's medical records to identify the choice of follow-up care and whether the woman attended her month 1 follow-up PrEP visit. The list will then be de-identified and provided to study staff. Among those who chose to remain with the LSU GYN residency program for their PrEP follow-up care, we will purposefully select three women who attended their month 1 follow-up PrEP care and three women who did not. Among those who chose to attend PrEP follow-up care with a routine PrEP provider, we will purposefully select three women who attended their month 1 follow-up PrEP care and three women who did not. We may need to modify the proposed participants to interview and the number of interviews per group based on patient

choices and retention outcomes during implementation (e.g., most patients chose the LSU GYN residency program for PrEP follow-up care, most patients did or did not attend month 1 follow up).

All interviews will be conducted via Zoom or on the telephone and audio-recorded with participant permission; we will take detailed notes for participants who wish not to be audio-recorded. We will use an encrypted recorder to audio-record interviews; interviews will not be video- or audio-recorded using Zoom. All audio files will be transcribed by GMR transcription.

PrEP Navigation Logs

Currently, logs documenting calls to existing PrEP navigators at SHHP from women in the community interested in PrEP are recorded at the Louisiana Department of Health. For our study, de-identified logs will be collected by the study team during each phase of the study to understand the volume of PrEP navigation interactions and potential linkages facilitated by the social media campaign.

7. Adaptation

We will conduct monthly feedback sessions throughout the study (e.g., at the end of each month-long rotation) with the LSU GYN residents and leadership. The purpose is to discuss their experiences with implementing the *Start the Conversation* initiative and make adaptations to the combined-care model (e.g. adjustments, additions and/or subtractions of action steps) as needed. The residents will receive information regarding their fidelity during the end of month feedback session and will have an opportunity to provide suggestions of components to change, add, or subtract to increase feasibility and acceptability. Residents and leadership will be informed that we will use information discussed at these meetings for research purposes (e.g., describing adaptations made during research dissemination). We will also use Epic data pulls of extractable data elements as needed to inform components that may need adaptation (e.g. was a PrEP conversation initiated, were shared decision-making talking points used).

8. Data analysis

We will evaluate the primary clinical outcomes using a difference-in-differences approach[6] to account for changes within time periods (pre- and post-implementation) and across sites (LSU versus Tulane). Poisson regression will be used to determine synergistic effects of the social media layering using weekly PrEP initiation counts, comparing uptake across implementation periods and sites and employing a product term to assess the impact of jointly implementing the combined-care model and social media campaign. We will analyze the secondary clinical outcomes using descriptive statistics.

We will use thematic analysis to analyze the qualitative data from the IDIs. Informed by the Proctor outcomes[5] and the Consolidated Framework for Implementation Research,[7] analysts will first develop a structural codebook based on predetermined topics explored during data collection. Next, content codes will be developed to capture emergent content. Transcripts will be coded by two or more analysts. Analysts will conduct inter-coder reliability assessments on approximately 25% of the transcripts; discrepancies will be resolved through discussion, codebooks will be updated as appropriate, and subsequent text will be recoded as needed.

NVivo software will be used to apply codes to transcripts. After coding, analysts will examine code frequencies across transcripts to 1) identify the most salient themes, and 2) create matrices to highlight the intersection or co-occurrence of deductive and inductive codes. We will focus on identifying which of the CFIR domains are most relevant to implementation, as well as how these codes interplay with Proctor's outcomes (acceptability, feasibility, appropriateness, and fidelity). An analytic report will be written to summarize findings.

9. Reimbursement

All GYN residents/leadership and women who participate in the interviews will receive $50.

10. Ethics

<u>In-depth interviews</u>

a. Informed Consent

We are asking for a waiver of written informed consent for the IDIs per federal regulations under 45 CFR 46.117(c)(1) which states that: *An IRB may waive the requirement for the investigator to obtain a signed informed consent form for some or all subjects if it finds any of the following:*

> *(i) That the only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject (or legally authorized representative) will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern;*
>
> *(ii) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context; or*
>
> *(iii) If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.*

We believe we qualify under ii above. Additionally, the regulation states: *In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects or legally authorized representatives with a written statement regarding the research.*

We will obtain oral consent from patients prior to their participation in the IDIs. We will provide residents and GYN leadership with an informational sheet, in replace of any consent (written or oral), that describes the purpose of the data collection activities and other related information (e.g., risks)**.**

b. Description of Risks

We do not believe that participating in the IDIs will lead to any physical, emotional, legal, or social harms. All potential participants will be informed that they are free to decline participation in the IDIs, and that their decision to participate or not participate has no impact on their health care. Participants will also be told that they can decline to answer any question during the IDI,

and can terminate their participation at any time. At the beginning of each IDI, we will remind participants again verbally that they can decline to answer and question or terminate their participation at any time. Participants can accept or decline to be audio-recorded during the IDIs; if participants choose not to be audio-recorded, detailed notes will be taken instead. The potential loss of confidentiality is a risk; participants will be informed that although every effort will be made to protect their privacy and to keep their information confidential, there is no guarantee that privacy and confidentiality can be fully maintained.

c. Anticipated Benefits

We do not anticipate any direct benefits to women from the IDIs. Patients, however, may appreciate or have a sense of satisfaction by contributing to developing strategies that may PrEP use among Black cisgender women in their community.

d. Protection of Confidentiality

Every effort will be made to protect participants' confidentiality; however, as with all research, there is no guarantee that confidentiality can be fully maintained.

The following procedures will be put in place to keep participant data confidential. First, participant names and contact information (collected for interview scheduling and facilitation purposes, and to disseminate study results) will not be recorded on any data collection instrument/transcript; a unique code will be assigned and used on all instruments/transcripts in place of participants' names. Second, participants will not be mentioned by name in any report or publication. Third, any hard copies of data will be logged and maintained in locked file cabinets when not in use. Access to the locked file cabinets will be limited to key research staff, who will pull materials only as needed to complete data entry, analysis, and management tasks. Fourth, all electronic data files and databases (Word, Excel, RedCap, Qualtrics) will be stored on a limited-access network drive in the Department of Population Health Sciences and shared with LSU via the secure Duke Box. Digital voice recordings from the interviews will also be stored securely on the Department of Population Health's network drives and on approved drives at the transcription company (GMR transcription). Audio-recordings will be destroyed after publication of the study's main findings. The link between study participants and study ID numbers will be destroyed when study activities are complete.

e. Protection of Privacy

We will suggest to participants that they find a private place for the Zoom- or telephone-based interview. Interviewers will also conduct the interviews in a private location. We will also protect participants' identities by password-protecting the central participant ID# log (that includes participants' names and contact information), storing it on a secure drive at LSU and Duke University, and limiting its access to a small number of staff.

Chart reviews

We do not anticipate any risks from abstracting data from provider notes on their use of the combined-care model. Only individuals who have existing access to provider and patient records will be engaged in the chart review (e.g., GYN residents and the PrEP Champions). All data provided to study staff will be de-identified. All LSU GYN residents will be informed that review of provider records will be conducted as part of the primary and secondary outcomes of the study and for the augmentation component. We will not obtain informed consent for the

chart reviews. Provider employment stability will not be directly impacted by the chart reviews, and residents' standing will not be impacted if they do not implement or inconsistently implement the combined-care model.

Electronic medical records

We do not anticipate any risks specific to Epic data pulls. All data provided to study staff will be de-identified. All data transferred from Epic will be stored on password-protected files only accessible to study personnel and stored on secure servers at LSUHSC. Each participant will be assigned a random study identification number. A separate password-protected log will be created linking the study ID numbers to the medical record numbers (MRN) of participants. The purpose of this log is to avoid duplication of charts, to allow researchers to return to charts to check the accuracy of the data contained in our files if necessary. The log linking study ID numbers to MRN will be destroyed when data analyses are complete. Any physical copies of data will be kept in locked filing cabinets at LSUHSC. Following publication and dissemination of the results, all data will be destroyed. We will also request a waiver of written consent and a HIPAA waiver. Our research could not practically be conducted without these waivers: the informed consent process could potentially affect potential participants' willingness to start PrEP and attend their follow-up PrEP visits because they know they are being monitored for research. Further, no identifiable information will be obtained by the study team.

PrEP Navigation Logs

Data from the SHHP PrEP navigation logs will be reported to study staff in aggregate numbers by gender and race; neither individual level records nor identifiable data will be collected by the research team. Informed consent will not be required for this activity as individual information will not be sought; only aggregate numbers reported from patient logs will be obtained.

11. Ethics Training

All study staff will have completed all required research ethics training prior to contact with any participant or their data.

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